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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,966	03/16/1999	ROBERTO CORREA	MO-5092/LEA	7814

7590 08/13/2002

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/13/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/254,966

Applicant(s)

CORREA ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed July 12, 2002 (Paper No. 18) in response to the Office Action of October 9, 2002 is acknowledged and has been entered. Claims 24-27 have been cancelled. Claims 1-8 and 13-23 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The rejection of claims 24-27, as they read on differentiating between infected and vaccinated animals, under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (Arch. Virol. 1994) and Lubroth et al. (Vaccine 1996) is **withdrawn** in view of Applicants cancellation of the claims.

The rejection of claims 1-8, 13-23 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is **maintained** for reasons of record. Applicant's arguments have been fully considered but are not found convincing. Applicants argument is directed to the Van Lierop et al. reference, the focus of the argument is that a peptide-based vaccine could possibly be developed even in light of the high degree of difficulty as disclosed by the reference.

To review the prosecution history the claims were originally rejected based on an obvious-type art rejection. In the interview, Paper No. 8, September 6, 2000, applicant argued the art rejection on the basis that the predictability of a vaccine can not be based on what

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epitopes the animal recognizes during a natural infection. In other words, an antibody response would not be indicative of a protective prophylactic effect in animal. In light of the arguments, if the examiner were to withdraw the art rejections' issues of predictably or lack thereof, could raise enablement concerns. Applicant will need to show possession of the claimed prophylactic effect of the peptides in the instant specification.

Applicant is now arguing the reverse, the same ELISA assay (shown in specification) now provides sufficient information to determine the prophylactic effect without testing the peptide vaccine in an animal. This is not convincing in light of the Van Lierop et al. reference, which clearly indicates that these vaccines must be tested to determine the efficacy, because it is not predictable how the peptides will be presented in the context of an MHC molecule. Therefore, the rejection is maintained for reasons of record. Applicant may overcome the rejection by showing the prophylactic effect of a peptide vaccine in an animal, the prophylactic effect will be limited to the specific formulation presented.

The rejection of claims 1-8 and 13-23 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention **is maintained**. Applicant's arguments and the Offices response are essentially the same as those of record. The specification has shown linear peptides that react with antibodies in the serum from vaccinated and infected animals. Based on the objective evidence that there is a need to test each peptide for efficacy as a vaccines formulation as indicated in the reference of Van Lierop et al. (Immunology 1995) and by applicants own

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arguments see interview summary of Paper No. 8, it is clear that the instant specification does not provide the requisite written description for a FMDV peptide based vaccine. Therefore, the rejection is maintained for the reason cited here and in the previous action.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

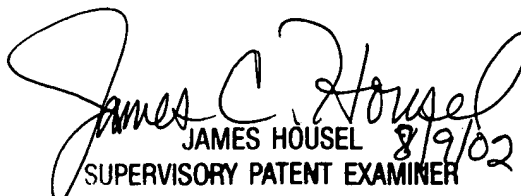
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.


JAMES HOUSEL 8/9/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600